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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,134	01/29/2001	David A. Lightfoot	1268/4/2	9557
25297	7590	05/09/2005	EXAMINER	
JENKINS, WILSON & TAYLOR, P. A. 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			KRUSE, DAVID H	
		ART UNIT	PAPER NUMBER	
		1638		

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/772,134	LIGHTFOOT ET AL.
	Examiner	Art Unit
	David H. Kruse	1638

The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

-- The Mail
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 February 2005.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11,13-15,17-26 and 71-81 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11,13-15,17-26 and 71-81 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Remarks/Res. to Mail Date 11/27/2003.

4) Interview Summary (PTO-1413)
Paper No(s)/Mail Date: _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 14 February 2005 has been entered.
2. The objection to the specification is withdrawn in view of Applicant's correction of the embedded hyperlink. The objection to the Abstract will be held in abeyance until the claims are deemed patentable and will be handled as outlined in MPEP § 1302.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claim 79 is objected to because of the following informalities: The phrase "of claims" at line 1 should read -- claim -- because the list is in the alternative. Appropriate correction is required.
5. Claim 22 is objected to because of the following informalities: The limitations "seeds" and "parts" should be in the singular because a claim should be limited to a single invention. Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. Claims 11, 13-15, 17-26 and 71-80 remain rejected and claim 81 is rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 February 2004. Applicant's arguments filed 14 February 2005 have been fully considered but they are not persuasive.

Applicants argue that the gene is capable of conveying *Heterodera glycines*-infestation resistance or *Fusarium solani*-infection resistance to a non-resistant soybean germplasm, the gene located within a quantitative trait locus mapping to linkage group G and mapped by genetic markers of SEQ ID NOs: 1-6, said gene located along said quantitative trait locus between said markers. Applicants also argue that BLASTP analysis of the translation of the rhg1 gene (Figure 7C), set forth as SEQ ID: 14 shows high homology to the T46070 GenBank entry described as hypothetical protein T18N14.120 from *Arabidopsis thaliana* (Figure 7E-7F), homology to the rice Xa21 disease resistance gene encoding a leucine-rich repeat protein, and homology to the tomato CF-2 gene for resistance to *Cladosporium fulvus* (paragraph spanning pages 12-13 of the Remarks). These arguments are not found to be persuasive. Because Applicant has not established that the specific DNA sequences encode a resistance function, it is unclear that Applicant has established a substantial or well-established utility for the claimed invention. There are no examples in the specification wherein Applicant has transformed a soybean plant with a DNA and conferred resistance upon

said transformed soybean plant. In addition, Applicant cannot require others to perfect the invention in order to establish a utility for a specific embodiment. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

Applicants argue that the instant claims are directed, *inter alia*, to isolated and purified nucleic acid molecules encoding a soybean Rhg4 gene. Applicants argue that the gene is capable of conveying *Heterodera glycines*-infestation resistance to a non-resistant soybean germplasm, the gene located within a quantitative trait locus mapping to linkage group A2 and mapped by the AFLP markers of SEQ ID NOs: 6-12, the gene located along said quantitative trait locus between said markers. Preferably, the gene comprises a nucleotide sequence set forth as any one of SEQ ID NOs: 16-19 (page 13, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given *supra*.

Applicants argue that it is clear that the assignment of function as recited in the present claims is based on a "reasonable correlation" between the homologies of the various proteins (page 14, 2nd paragraph of the Remarks). This argument is not found to be persuasive because similarity to a "hypothetical protein" does not establish a

function and the similarity to the other recited proteins does not appear to establish a correlation between structure and function.

Applicants argue that the presently claimed subject matter has utility in providing resistance to other plant species, particularly in view of Whitham S, McCormick S, and Baker B. Proc Natl Acad Sci U S A. 1996 93(16): 8776-81, which shows that resistance genes from tobacco can work in tomato (page 15, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Applicants have established that the claimed rhg1 or Rhg4 gene products are homologous in function to that taught by Whitham *et al* (1996) and Applicants have not provided evidence that they have in fact isolated an rhg1 or Rhg4 gene.

Claim Rejections - 35 USC § 112

7. Claims 11, 13-15, 17-26 and 71-80 remain rejected and claim 81 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and use the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 February 2004. Applicant's arguments filed 14 February 2005 have been fully considered but they are not persuasive.

Applicants argue that SEQ ID NOs: 13 and 14 (Figure 7) show an entire coding region for the protein encoded by the gene found in soybean roots (page 16, 3rd paragraph of the Remarks). This argument is not found to be persuasive because it

would have been clear to one of skill in the art at the time of Applicant's invention that the amino acid sequence taught in SEQ ID NO: 14 does not represent a complete protein sequence, as it is clear that the N-terminal portion is not taught.

Applicant's arguments concerning the SCN host range does not appear to be relevant to the instant rejection, the instant rejection is directed to a lack of enablement (paragraph spanning pages 16-17 of the Remarks).

Applicants argue that the guidance for identifying and isolating a nucleic acid encoding an SCN/SDS resistance polypeptide is sufficient, contrary to the contentions of the Patent Office on page 7 of the Official Action, and that when taken together, Examples 3 and 4 clearly demonstrate to the skilled artisan the identification and isolation of a nucleic acid encoding an SCN/SDS resistance polypeptide (page 17, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given *supra*. Applicants provide no evidence of function, do not teach any transgenic plants, and do not teach a complete coding sequence. Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use the invention as claimed.

8. Claims 11, 13-15, 17-26 and 71-80 remain rejected and claim 81 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last

Office action mailed 13 February 2004. Applicant's arguments filed 14 February 2005 have been fully considered but they are not persuasive.

Applicants argue that in the instant specification, the biomolecule is not described solely by a functional characteristic. Applicants argue that sentence data for the genes themselves is also included. Applicants further argue that between SEQ ID NO: 13, which corresponds to Rhg1 and any one of SEQ ID NOs: 16-19, which correspond to Rhg4, there is over 98% sequence identity, and that one of ordinary skill in the art would recognize that there is a disclosed correlation between the function described and the structure of the sequence (page 19, 2nd paragraph of the Remarks). These arguments are not found to be persuasive because the instant Application only describes how one of skill in the art may be able to find an SCN or a SDS polypeptide encoding nucleic acid, the instant Application does not describe such nucleic acids. The Examiner maintains that SEQ ID NO: 13 does not adequately describe an Rhg1 gene product such that one of skill in the art would have recognized that Applicants had possession of such a gene as claimed. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not

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establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 11, 14, 21, 24, 25, 71, 74 and 81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 14, 21, 24, 25, 71, 74 and 81 are indefinite because there is nothing in the teachings of the instant application that demonstrates that a single resistance polypeptide can have biological activity against soybean cyst nematode infestation and sudden death syndrome (SCN/SDS). The metes and bounds of this claim are unclear given the teachings of Applicants and the art in general.

At claims 14(b), 24(b), 25(b), 74(b) and 81(c), the limitation "having a nucleotide sequence substantially identical to" renders the claims indefinite because it is unclear what the metes and bounds of "substantially identical to" are.

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Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.

29 April 2005

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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